

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): SCHASTEEN *et al.*
Application No.: 10/652,745
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Art Unit: 1617
Examiner: S. Kantamneni
Title: ANTIMICROBIAL
COMPOSITIONS

**ISSUES TO BE DISCUSSED AT
EXAMINER INTERVIEW (MPEP § 713.01)**

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to MPEP § 713.01, the Applicants hereby indicate in advance what issues are to be discussed at the interview by submitting, in writing, a proposed amendment:

Claim 75. (Proposed Amendment) A method of inhibiting or killing microbes comprising Salmonella in food ~~or water~~, the method comprising treating the food ~~or water~~ with a composition, the composition comprising 2-hydroxy-4-(methylthio)butanoic acid and at least two organic acids selected from the group consisting of formic acid, butyric acid, fumaric acid, lactic acid, benzoic acid, and propionic acid.

The Applicants respectfully request that the proposed amendment be considered in view of the following: (1) the experimental evidence and declaration, previously of record, which show an unexpected result; and, (2) the prior art teachings away that further support the unexpected result of Applicants' claimed invention.

(1) Experimental Evidence and Declaration of Record

- Attached is a graph identified as Figure 7, which shows that the Applicants' claimed composition shows dramatic improvement in antimicrobial activity against Salmonella in feed. The synergistic effect reflected by the data is both unexpected and beyond any of the individual components similarly tested.
- Data showing unexpected result:
 - (a) 0.45% HMTBA alone;
 - (b) 0.45% butyric acid alone;
 - (c) 0.45% lactic acid alone;
 - (d) 0%, 0.25%, 0.5%, 0.75%, and 1.0% propionic alone (separate graph, also attached);
 - (e) blend OA 4, which is 0.15% lactic acid, 0.15% propionic acid, and 0.15% HMTBA; and
 - (f) blend OA 6, which is 0.1% lactic acid, 0.1% butyric acid, 0.1% propionic acid, and 0.15% HMTBA.
- Also attached is the Declaration of Dr. Christopher Knight, submitted on September 26, 2007, which emphasizes the unexpected result shown in the data. The following excerpt is from Dr. Knight's submitted declaration at paragraph four:

"With reference to the attached graph, data is depicted for the antimicrobial activity of five different organic acid compositions against Salmonella in feed. The five organic acid compositions include: (1) 0.45% HMTBA alone (i.e., 2-hydroxy-4-(methylthio)butanoic acid, which is a compound of Formula (I) in the '434 application); (2) 0.45% butyric acid alone; (3) 0.45% lactic acid alone; (4) blend OA 4, which is 0.15% lactic acid, 0.15% propionic acid, and 0.15% HMTBA; and (5) blend OA 6, which is 0.1% lactic acid, 0.1% butyric acid, 0.1% propionic acid, and 0.15% HMTBA . . .

As depicted in the graph, the antimicrobial activity of either blend OA 4 or blend OA 6 achieved significantly higher killing of

**Salmonella at lower concentrations than could be achieved with
any of the single organic acids alone.”**

(2) Prior Art Teaching Away

- Enthoven *et al.* disclose that 2-hydroxy-4-(methylthio)butanoic acid and formic acid are **not effective as antibacterial agents** against *Salmonella*. In particular the abstract discloses “the results show there is **no inhibitory effect of HMB** (i.e., 2-hydroxy-4-(methylthio)butanoic acid) **or formic acid on Lactobacillus or Salmonella.**”
- Bland *et al.* disclose that lactic acid, propionic acid, formic acid, butyric acid, sorbic acid, benzoic acid and combinations of these are **not effective as antibacterial agents against Salmonella in feed**. In particular Bland et al state: “[M]any compounds with known bacteriocidal properties, such as **lactic acid, propionic acid, formic acid, butyric acid, sorbic acid, benzoic acid and combinations** of these have been tested. While many of these agents kill bacteria in solution, **they do not kill all the bacteria in animal feedstuffs**. Woolford, M. K., "Microbiological Screening of Food Preservatives, Cold Sterilants and Specific Antimicrobial Agents as Potential Silage Additives", J. Sci. Ed. Agric. 1975, 26, 229-237. **To be effective against Salmonella, a bacteriocidal treatment must kill essentially all of the bacteria. Methods that kill 95% or even 99% are largely ineffective because the residual bacteria can multiply rapidly and recontaminate the feedstuff**, and eventually the entire processing facility.”

The issues to be discussed at the upcoming interview are the proposed amendment and the allowance of all pending claims. No fees are believed to be due in connection with the filing of this document, however, should any fees be deemed necessary for any reason relating to this document, the Commissioner is hereby authorized to deduct the fees from the Polsinelli Shughart PC Deposit Account No. 50-1662, referencing the above docket number.

PATENT

Application No.: 10/652,745
Attorney Docket No.: 048968-117961
Via EFS-Web

Polsinelli Shughart PC

Respectfully submitted,

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